I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL IN AN ENVELOPE ADDRESSED TO: MAIL STOP NON FEE AMENDMENT, COMMISSIONER FOR PATENTS, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450, ON THE DATE INDICATED BELOW.

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PATENT

MAIL-STOP NON FEE AMENDMENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Patent Application of

Boris Skurkovich et al.

Appln. No.: 10/603,507

Filed:

June 25, 2003

For: TREATMENT OF SCHIZOPHRENIA

: Group Art Unit: 1653

: Examiner: Not Yet Assigned

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INFORMATION DISCLOSURE STATEMENT

It is requested that the references listed on the attached Information Disclosure Citation Form PTO-1449 be considered by the Patent Examiner in connection with the above-identified application and be made of record therein.

Copies of the references were previously cited by and/or submitted to the U.S. Patent and Trademark Office in related Application No. 10/422,119 filed April 24, 2003 (the "prior application"). The present application relies, under 35 U.S.C. § 119(e), on the filing date of U.S. Provisional Application No. 60/411,925, filed September 18, 2002. Therefore, under 37 C.F.R. § 1.98(d), copies of the references are not enclosed.

Independent consideration and acknowledgment of the listed reference(s) is respectfully requested.

Respectfully submitted,

BORIS SKURKOVICH ET AL.

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Sheet	1	of	6

Complete if Known			
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First Named Inventor	Boris Skurkovich		
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Examiner Name	Not Yet Assigned		
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	U.S. PATENT DOCUMENTS					
Exr Initials	U.S. Patent Document Number	Kind Code (if known)	Name of Inventor or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY		
	4,362,155		Simon V. Skurkovich	Dec. 7, 1982		
	4,605,395		Christian Sainte Rose et al	August 12, 1986		
_	5,800,988		Cecile Casterman et al.	September 1,1998		
	5,759,808		Cecile Casterman et al.	June 2, 1998		
	5,840,526		Cecile Casterman et al.	November 24, 1998		
	6,015,695		Cecile Casterman et al.	June 18, 2000		
	4,704,362		Keiichi Itakura et al	November 3, 1987		
•	4,824,432		Simon Skurkovich et al	April 25, 1989		
	6,180,370		Cary L. Queen et al	January 30, 2001		
	6,329,511		Maximiliano Vasquez et al.	December 22, 2001		
	5,888,511		Simon V. Skurkovich	March 30, 1999		

			FOREIGN PATE	NT DOCUMENTS		
Exr Initials	Foreign Patent Document				Date of	٦
	Country Number Code		Kind Code (if known)	Name of Inventor or Applicant of Cited Document	Publication of Cited Document MM-DD-YYYY	
	WO	87/02671		Randy Robinson et al	May 7, 1987	

	OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS	
Exr Initials	Include Name of Author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal., serial., symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T,
	ADERKA et al., Correlation Between Serum Levels of Soluble Tumor Necrosis	
	Factor Receptor and Disease Activity in Systemic Lupus Erythematosus, Arthritis	
	and Rheumatism, Vol. 36, No. 8, 1111-1120 (August, 1993)	
	ALTOMONTE et al., Serum Levels of Interleukin-1b, Tumour Necrosis Factor-a	
	and Interleukin-2 in Rheumatoid Arthritis: Correlation With Disease Activity, Clin. Rheum. Vol. 11, No. 2, pp. 202-205, (1992)	
	· · · · · · · · · · · · · · · · · · ·	-
	AROLT et al., Decreased in vitro production of interferon-gamma and interleukin-	l
	2 in whole blood of patients with schizophrenia during treatment, Molecular	
	Psychiatry, Vol. 5, 150-158 (March, 2000)	L
	BAYER et al., The Avidin-Biotin Complex in Affinity Cytochemistry, Methods in Enzymology, Vol. 62:308 (1979), Academic Press, Inc. (Book; Not Submitted)	•
	BEVAN et al., Interferon-Induced Parotitis and Epididymitis, The Lancet 2:561	H
	(September, 1985)	
	BEYCHOK, Cells of Immunoglobulin Synthesis, (1979) Academic Press, New York	•
	(Book; Not Submitted)	
-	BIGLINO et al., Spontaneous Release of Interferon as a Predictor of Clinical	
	Evolution in HIV-Positive Subjects, Infection 19(I): 7/11-11/17 (1991)	
	BIRD et al., Single-Chain Antigen-Binding Proteins, Science Vol. 242, pp. 423-426,	
	April, 1988.	L
	BRAHN et al., Effects of Tumor Necrosis Factor Alpha (TNF-α) on Collagen	

1	Arthritis, Lymphokine and Cytokine Research, Vol. 11, No. 5 pp. 253-256, (1992)	
]	BRENNAN et al., TNFa - A Pivotal Role in Rheumatoid Arthritis?, British Journal	
(of Rheumatology, 31(5):293-298 (1992)	
1	BURTON, Dennis R., Human Monoclonal Antibodies: Achievement and Potential,	Γ
]	Hospital Practice, pp. 67-74, August 1992.	l
(CAMPBELL, A.M., Monoclonal Antibody Technology: Laboratory Techniques in	Γ
]	Biochemistry and Molecular Biology, Elsevier Science Publishers Amsterdam, The	
	Netherlands (1984) (Book; Not Submitted)	
	CARPENTER et al., The Pathogenesis of Autoimmunity in New Zealand Mice, Lab	
	Invest. Vol. 23, No.6, pp 628-634, (1970)	İ
-	CHU et al., Detection of Cytokines at the CartilAge/Pannus Junction in Patients	T
	With Rheumatoid Arthritis: Implications for the Role of Cytokines in Cartilage	
	Destruction and Repair, British Journal of Rheumatology, Vol. 31, No. 10 pp. 653-	
	661 (1992)	
_	CONLON et al., Exacerbation of Symptoms of Autoimmune Disease in Patients	t
	Receiving Alpha-Interferon Therapy, Cancer, Vol. 65, pp. 2237-2242, May 15, 1990.	l
	DANIS et al., Circulating Cytokine Levels in Patients With Rheumatoid Arthritis:	t
	Results of a Double Blind Trial With Sulphasalazine, Ann. Rheum. Disease	
	51(8):946 (1992)	l
	DIAGNOSTIC AND STATISTICAL MANUAL OF PSYCHIATRIC DISORDERS	t
	(DSM IV) American Psychiatric Association, 4th Ed. Washington D.C. (1994)	
		l
_	(Book; Not Submitted)	ł
	DELEURAN et al., Localization of Tumor Necrosis Factor Receptors in the	
	Synovial Tissue and Cartilage-Pannus Junction in Patients With Rheumatoid	l
-	Arthritis, Arthritis and Rheumatology, Vol. 35, No. 10, pp. 1170-1178 (1992)	ł
	DeSTEFANO et al., Acid-Labile Human Leukocyte Interferon in Homosexual Men	l
	With Kaposi's Sarcoma and Lymphadenopathy, The Journal of Infectious Diseases,	l
	Vol. 146, No. 4, pp. 451-455, October, 1982.	╀
	DORSETT et al., Anti-Lymphocyte Antibodies in Patients With the Acquired	l
	Immune Deficiency Syndrome, The American Journal of Medicine, Vol. 78, pp.	l
	621-626,	l
	April, 1985.	ł
	ELLIOTT et al., Treatment of Rheumatoid Arthritis With Chimeric Monolonal	
	Antibodies to TNF-α Safety, Clinical Efficacy and Control of the Acute-Phase	
	Response, J. Cell. Biochem. Suppl. 17B:145 (1993).	1
	ELLIOTT et al., Repeated Therapy With Monoclonal Antibody to Tumour	
	Necrosis Factor α (cA2) in Patients With Rheumatoid Arthritis, The Lancet, Vol.	
	344, pp. 1125-1127, October 22, 1994.	1
	ENGLEMAN et al., Treatment of NZB/NZW F1 Hybrid Mice With Mycobacterium	
1	Bovis Strain BCG or Type II Interferon Preparations Accelerates Autoimmune	
	Disease, Arthritis and Rheumatism, Vol. 24, pp. 1396-1402, November, 1981.	
	biscusse, the time and tenedimensing von 2 is ppt 1000 1 iou, 110	
]	ENGVALL et al., Enzyme-Linked Immunosorbent Assay, Elisa III. Quantitation of	T
]		
]	ENGVALL et al., Enzyme-Linked Immunosorbent Assay, Elisa III. Quantitation of	

	FATTOVICH et al., Autoantibodies During α-Interferon Therapy for Chronic Hepatitis B, Journal of Medical Virology, Vol. 34, pp. 132-135, (1991)	
	FELDMANN et al., Interferons and Autoimmunity, IFN9, Academic Press, p. 75 (1987)	
	FOULIS et al., Immunoreactive α-Interferon in Insulin-Secreting β Cells in Type 1	
	Diabetes Mellitus, The Lancet, Vol. 2, pp. 1423-1427, December 19, 1987.	
	GAUGHRAN, Immunity and schizophrenia: autoimmunity, cytokines, and immune responses, Int Rev Neurobiol. 2002, 52:275-302.	
	GENDELMAN et al., Induction of IFN-α in Peripheral Blood Mononuclear Cells	
	by HIV-Infected Monocytes, The Journal of Immunology, Vol. 148, pp. 422-429,	
	January 15, 1992.	
	GILLAM et al., Site-Specific Mutagenesis Using Synthetic	
	Oligodeoxyribonucleotide Primers: I. Optimum Conditions and Minimum	
	Oligodeoxyribonucleotide Length, Gene Vol. 8, pp. 81-97 (1979), Elsevier/North- Holland Biomedical Press	
	GODING, Conjugation of Antibodies With Fluorochromes: Modifications to the	
	Standard Methods, Journal of Immunological Methods, 13:215-226 (1976),	
	Elsevier/North-Holland Biomedical Press.	
	GRANINGER et al., Induction of Systemic Lupus Erythematosus by Interferon-γ in	
	a Patient With Rheumatoid Arthritis, The Journal of Rheumatology, Vol. 18, pp.	
	1621-1622, 1991.	
	GRINGERI et al., Anti-Alpha Interferon Immunization: Safety and	
	Immunogenicity in Asymptomatic HIC Positive Patients at High Risk of Disease	
	Progression, Cellular and Molecular Biology, Vol. 41, No.3, pp. 381-387 (1995)	
	GRINGERI et al., Absence of Clinical, Virological, and Immunological Signs of	
	1	
	Progression in HIC-1-Infected Patients Receiving Active Anti-Interferon-α	
	Immunization: A 30-Month Follow-up Report, Journal of Acquired Immune	
	Deficiency Syndromes and Human Retrovirology, 13:55-67 (1996)	
	GU et al., Construction and Expression of Mouse-human Chimeric Antibody SZ-51 Specific for Activated Platelet P-selectin, Thrombosis and Hematocyst 77 (4):755-759 (1997)	
·	HAMERS-CASTERMAN et al., Naturally occurring antibodies devoid of light	
	chains. Nature. 1993 June 3 363(6428):446-448.	
	HARLOW et al., In Antibodies: A Laboratory Manual, Cold Spring Harbor, NY (Book; Not Submitted)	•
	HENNIGER et al., Interferon-β _{1b} Treatment Decreases Tumor Necrosis Factor-α	
	and Increases Interleukin-6 Production in Multiple Sclerosis, Neurology Vol. 46,	
	1633-1639, June 1996	
- · - · ·	HEREMANS et al., Interferon Treatment of NZB Mice: Accelerated Progression of	
	Autoimmune Disease, Infection and Immunity, Vol. 21, pp. 925-930, Printed in	
	USA, September 1978.	
	HESS et al., Tumor Necrosis Factor and Interferon as Prognostic Factors in Human	
	Immunodeficiency Virus (HIV) Infection, Infection 19, Suppl 2:S93-97 (1991)	
	HIRANO et al., Interleukin-6 and Its Relation to Inflammation and Disease,	
	Clinical Immunology, and Immunopathology, Vol. 62, No. 1, pp.S60-S65, January, 1992., Academic Press, Inc.	
	1772., Academic 1 1000, 1110.	

HOLT et al., Cytokine Inter-Relationships and Their Association With Disease
 Activity in Arthritis, British Journal of Rheumatology, Vol. 31, pp. 725-733, (1992).
HOOKS et al., Immune Interferon in the Circulation of Patients With Autoimmune
 Disease, The New England Journal of Medicine, Vol. 301, No. 1, July 5, 1979.
HUSTON et al., Protein Engineering of Antibody Binding Sites: Recovery of
Specific Activity in an Anti-Digoxin Single-Chain Fv Analogue Produced in
Escherichia Coli, Proc. Nat'l. Acad. Sci. USA, Vol 85, pp. 5879-5882, August, 1988
 JOHNSON et al., The Role of Antimyosin Antibodies in Acute Myocardial
Infarction, Seminars in Nuclear Medicine, Vol. 19, No. 3, pp. 238-246, July, 1989.
LARREY et al., Exacerbation of Multiple Sclerosis After the Administration of
Recombinant Human Interferon Alfa, JAMA, Vol. 261, p. 2065, April 14, 1989.
 LAU et al., Regulation of Tumor Necrosis Factor Receptor Expression by Acid-
Labile Interferon-α From AIDS Sera, AIDS Research and Human Retroviruses,
Vol. 7, No. 6, pp.545-552, 1991, Mary Ann Liebert, Inc., Publishers.
 LEINONEN et al., Circulating Immune Complexes Containing Chlamydial
Lipopolysaccharide in Acute Myocardial Infarction, Microbial Pathogenesis, Vol. 9,
pp. 67-73, 1990
 LIBIKOVA et al., Orbiviruses of the Kemerovo Complex and Neurological
Diseases, Med. Microbiot. Immun, Vol. 166, pp. 255-263 (1978)
LIBIKOVA et al., Assay of Interferon and Viral Antibodies in the Cerebrospinal
Fluid in Clinical Neurology and Psychiatry, Acta Biol. Med. Germ., Band 38, Seite
879-893 (1979)
LINK et al., Increased Transforming Growth Factor-β, Interleukin-4, and
Interferon-γ in Multiple Sclerosis, American Neurological Association, Vol. 36, pp.
 379-386 (1994)
LIVDEN, et al., In Situ Localization of Interferons in Psoriatic Lesions, Arch
 Dermalot Res. 281, pp. 392-397, (1989)
MACHOLD et al., Interferon-γ Induced Exacerbation of Systemic Lupus
 Erythematosus, J. Rheumat. 17(6):83 1-832 (1990)
MATSUYAMA et al., Cytocidal Effect of Tumor Necrosis Factor on Cells
Chronically Infected with Human Immunodeficiency Virus (HIV): Enhancement of
 HIV Replication, Journal of Virology, Vol. 63, No. 6, June 1989, pp. 2504-2509
MEIJER et al., Profiles of Cytokines (TNFα and IL-6) and Acute Phase Proteins
(CRP and \alpha 1AG) Related to the Disease Course in Patients With Systemic Lupus
Erythematosus, Lupus, Vol. 2, pp. 359-365, 1993.
 MONTALBAN et al., Antiphospholipid Antibodies in Cerebral Ischemia, Stroke,
Vol. 22, pp. 750-753 (1991)
NAUDIN et al., A differential role for interleukin-6 and tumor necrosis factor-alpha
in schizophrenia? Schizophr Res. 1997 Aug 29;26(2-3):227-33.
PANITCH et al., Exacerbations of Multiple Sclerosis in Patients Treated With
Gamma Interferon, The Lancet 1:893, April 18, 1987.
 PAULUS et al., Analysis of Improvement in Individual Rheumatoid Arthritis
Patients Treated With Disease-Modifying Antirheumatic Drugs, Based on the
Findings in Patients Treated With Placebo, Arthritis Rheum. 33:477-484(1990)
PREBLE et al., Systemic Lupus Erythematosus: Presence in Human Serum of an
Unusual Acid-Labile Leukocyte Interferon, Science, Vol. 216, No. 23, pp. 429-431,
1

 A	T
 April 1982.	╀
PREBLE et al., Serum Interferon in Patients With Psychosis, Am. J. Psychiatry 142:10 October, 1985.	
 QUEEN et al., Cell-Type Specific Regulation of a & Immunoglobulin Gene by	\vdash
Promoter and Enhancer Elements, Immunol. Rev., 89, 49-68 (1986)	ł
 QUESADA et al., Clinical Toxicity of Interferons in Cancer Patients: A Review,	T
Journal of Clinical Oncology, Vol. 4, No. 2, pp. 234-243, February, 1986.	
 QUESADA et al., Psoriasis and Alpha-Interferon, The Lancet 2:1466, June 28,	T
1986.	
REMY et al., Experimental Autoimmune Thyroiditis Induced by Recombinant	
Interferon-γ, Immunology Today, Vol. 8, No. 3, 73 (1987)	
ROBERTS et al., Generation of an Antibody With Enhanced Affinity and	Γ
Specificity for its Antigen by Protein Engineering, Nature, 328:731-734 (1987)	
RONNBLOM, et al., Possible Induction of Systemic Lupus Erythematosus by	
Interferon-a Treatment in a Patient With a Malignant Carcinoid Tumour, Journal	
of Internal Medicine, Vol. 227, pp. 207-210 (1990)	
RONNBLOM et al., Autoimmunity After Alpha-Interferon Therapy for Malignant	
Carcinoid Tumors, Annals of Internal Medicine, Vol. 115, 178-183 (1991)	
 SAMBROOK et al., 1989, Molecular Cloning, A Laboratory Manual, Cold Spring	T.
Harbor, NY. (Book; Not Submitted)	
SASTRY et al., 1989, Cloning of the immunological repertoire in Escherichia coli	T
for generation of monoclonal catalytic antibodies: construction of a heavy chain	
variable region-specific cDNA library. Proc. Nat'l. Acad. Sci. USA, 86: 5728-5732	L
SCHATTNER et al., Review: Interferons and Autoimmunity, Am. J. Med. Sci. Vol.	
295, No. 6, pp. 532-544, June, 1988.	L
SCHILLING et al., Development of Systemic Lupus Erythematosus After	
Interferon Therapy for Chronic Myelogenus Leukemia, Cancer Vol. 68, pp. 1536-	
1537, October 1, 1991.	L
SCOPES et al., Protein Purification, Springer-Verlag, New York, NY (1982) (Book;	
 Not Submitted)	╀
SELIGMANN et al., 1979, Heavy chain diseases: current findings and concepts.	
 Immunological Review 48: 145-167	+
SHARIEF et al., Association Between Tumor Necrosis Factor-α and Disease	
Progression in Patients With Multiple Sclerosis, The New England Journal of	
Medicine, Vol. 325, No. 7, pp. 467-472 August 15, 1991.	+
SHIOZAWA et al., Interferon-Alpha in Lupus Psychosis, Arthritis and	
 Rheumatism, Vol. 35, pp. 417-422, April, 1992. SINHA et al., Autoimmune Diseases: The Failure of Self Tolerance, Science, Vol.	+
248, pp. 1380-1387, June 15, 1990.	
 SKURKOVICH et al., Immunosuppressive Effect of an Anti-interferon Serum,	\dagger
Nature, Vol. 247, pp. 551-552, February 22, 1974	
 SKURKOVICH et al., The Probable Role of Interferon in Allergy, Annals of	\dagger
Allergy Vol. 35, pp. 356-360, December, 1975.	
 SKURKOVICH et al., Lymphocytes' Cytotoxicity Towards Cells of Human	t
Lymphoblastoid Lines in Patients With Rheumatoid Arthritis and Systemic Lupus	
Erythematosus, Annals of Allergy Vol. 39, pp. 344-350, November, 1977.	1

	OVICH et al., Interferon Production by Patients With Systematic Lupus	
Erythen	natosus (SLE) or Rheumatoid Arthritis (RA), Abstracts – Second Annual	
Internat	ional Congress for Interferon Research (1981)	
SKURK	OVICH et al., Aberrant IFN May Help HIV Survive and Replicate; Its Removal in	
AIDS Pa	atients May Halt This Process and Help Restore the Immune System, Journal of	
	on Research, Vol. 12, Suppl. 1:S110 (1992)	
	OVICH et al., A Disturbance of Interferon Synthesis With the Hyperproduction of	
	Kinds of Interferon can Trigger Autoimmune Disease and Play a Pathogenetic	
	AIDS: The Removal of These Interferons Can Be Therapeutic, Medical Hypotheses,	
I i	pp. 177-185 (1993)	
	OVICH et al., A Disturbance of Interferon Synthesis With the Hyperproduction of	
	Kinds of Interferon can Trigger Autoimmune Disease and Play a Pathogenetic	
	AIDS: The Removal of These Interferons Can Be Therapeutic, Medical Hypotheses,	
	ypoth. Vol. 42, pp. 27-35 (1994)	
	BERGER et al., The Unlabeled Antibody Enzyme Method of	
	whistochemistry Preparation and Properties of Soluble Antigen-Antibody Complex	
1 '	adish Peroxidase-Antihorseradish Peroxidase) and its use in Identification of	
	etes The Journal of Histochemistry and Cytochemistry, Vol. 18, No. 5, pp. 315-333	
	OTH et al., Production of Monoclonal Antibodies: Strategy and Tactics, Journal of	
	ological Methods, Vol. 35k, pp. 1-21 (1980)	<u> </u>
	NSKI et al., Thrombospondin Promotes Platelet Aggregation, Blood, Vol. 72, pp.	
	, July, 1988.	<u> </u>
i i	N-RAJ et al., Immunological Variables as Predictors of Prognosis in Patients With	
	Sarcoma and the Acquired Immunodeficiency Syndrome, Cancer Research, Vol.	
	17-425, January 1986.	
ł I	IICK et al., Interleukin-6: An Overview, Annual Rev. Immunol. Vol. 8, pp. 253-278	
(1990)		
VILCEI	K et al., In AIDS: The Epidemic of Karposi's Syndrome and Opportunistic	•
Infection	ns, A. E. Friedman-Kien & L. J. Lauberstein, eds. Masson Publishing, NY, NY	
(1986)		
	et al., 1989, Binding activities of a repertoire of single immunoglobulin variable	
	s secreted from Escherichia coli. Nature, 341: 544-546	
	et al., In Situ Hybridization of IL-6 in Rheumatoid Arthritis, Clin & Exp. Immunol	
87(2):18	· · · · · · · · · · · · · · · · · · ·	
	ACKER, 1987, "From Genes to Clones," VCH Publishers, New York, N.Y	•
	Not Submitted)	1
		-
	IT et al., Genetically Engineered Antibodies: Progress and Prospects, Critical Rev.	
in Immi	ınol. 12(3,4):125-168 (1992)	

• References are books